Reported side effects following COVID-19 vaccination in Canada

We update this page every Friday at 12:00 PM Eastern Time. A summary and background information are available.

This report was last updated on July 22, 2021 with data up to and including July 14, 2021.

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What you need to know

up to and including July 14, 2021

One potential new safety signal has been identified in Canada
(see summary for as mentioned)

46,694,799
Total doses administered

10,167
Total adverse event following immunization reports
(0.0218% of all doses administered)

7,726
Total adverse event following immunization reports that were non-serious
(0.0175% of all doses administered)

2,441
Total adverse event following immunization reports that were serious
(0.0053% of all doses administered)

289
New adverse event following immunization reports since last update
(138 new non-serious and 151 new serious)

- The benefits of vaccines authorized in Canada continue to outweigh the risks.
- Health Canada, the Public Health Agency of Canada (PHAC), the provinces and territories, and manufacturers continue to closely monitor the safety of COVID-19 vaccines. We'll respond to any safety issues right away and will share information with you as we learn more about these vaccines.
- Of the **10,167** individual reports (**0.0218% of all doses administered**), **2,441** were considered serious (**0.0053% of all doses administered**).

Safety issue updates

- A case of thrombosis with thrombocytopenia syndrome following vaccination with AstraZeneca/COVISHIELD (COVID-19 vaccine) continue to be monitored. Health Canada has updated the product monograph to include information on potential cases of this very rare event of blood clots associated with low platelets and bleeding following immunization.
- The Public Health Agency of Canada (PHAC) and Health Canada are also monitoring Canadian and international reports of myocarditis and pericarditis following vaccination with mRNA vaccines (Pfizer-BioNTech and Moderna vaccines). Signs and symptoms of myocarditis and pericarditis, inflammation of the heart muscle and pericardium (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. Data in Canada are now indicating a slightly higher number of cases in young males than would normally be expected in the general population. Health Canada recently updated the product monographs for both Moderna and Pfizer COVID-19 vaccines to include information around these risks. Health Canada and PHAC continue to monitor the evolving information regarding the association between myocarditis/pericarditis and mRNA vaccines.
- Health Canada, PHAC and provinces and territories have been assessing reports of adverse events related to capillary leak syndrome and the Moderna COVID-19 vaccine. Health Canada has updated the product monographs to include information on capillary leak syndrome, including a contraindication for patients who have previously experienced this syndrome. PHAC and Health Canada have also updated the Guillain-Barré Syndrome Quick Reference Guide (QRG) in Canada following Moderna COVID-19 vaccination and have observed a higher number of cases than would normally be expected in the general population. Health Canada and provinces and territories are working closely with the manufacturers and international regulators to review information as it becomes available and will take appropriate action.

Definitions

- Adverse Event Following Immunization (adverse event)
- Adverse event report
- Serious adverse event
- Medically important event
- Adverse Events of Special Interest (AESI)
- Safety signal

How to report an adverse event

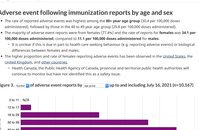
If you experience a adverse event following immunization with a COVID-19 vaccine in Canada, please contact your healthcare provider. Learn more about reporting adverse events.

Summary of adverse event following immunization reports

The following information is based on reports received in Canada from the Public Health Agency of Canada's Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) and the Health Canada Vigilance program. Doses administered used for rate calculations have been adjusted to account for the delay between vaccination and reporting. The data on this page may differ from provincial and territorial reports due to different timelines.

There have been a total of **10,167** reports (**26.1 reports per 100,000 doses administered**) up to and including July 14, 2021. Of the **10,167** reports, **2,441** were considered serious (**6.3 reports per 100,000 doses administered**). While the number of doses administered have increased over time, the rate of serious reports has remained low. The cumulative and weekly reports are shown below, as well as the weekly reports, are shown in Figure 1.

Figure 1. Weekly reports **COVID-19 vaccine adverse event reports and total doses administered per week up to and including July 14, 2021** (n=10,167)



Data table: This chart contains the following data:

- Figure 1: Text Description

Adverse event following immunization reports by vaccine name

Figure 2 shows the breakdown of reports by vaccine name. For doses administered by vaccine type, please visit the Vaccination Coverage report. COVID-19 vaccines approved for use in Canada currently include:

- Pfizer-BioNTech
- Moderna
- AstraZeneca
- COVISHIELD (a version of the AstraZeneca vaccine manufactured by the Serum Institute of India and approved in Canada by Health Phareceuticals Inc.)
- Janssen (Johnson and Johnson)

Note the Janssen vaccine has been approved for use in Canada, it has not yet been distributed during this reporting period.

Higher rates of non-serious adverse event reports are observed for each vaccine, with serious report rates continuing to remain low. Currently, rates of adverse events following the second dose are lower than after the first dose. The data for mixed vaccine products are too limited to make any comparisons between products. In general, the reported non-serious adverse events are consistent with information provided in the vaccine product usage.

Figure 2. Total **adverse event reports** by vaccine name and dose number up to and including July 14, 2021 (n=10,167)

Data table: This chart contains the following data:

- Figure 2: Text Description

Adverse event following immunization reports by age and sex

- The rate of reported adverse events was highest among the **80 year age group** (56.4 per 100,000 doses administered), followed by those in the 70-79 year age group (39.8 per 100,000 doses administered).
- The majority of adverse event reports were from females (77) and the rate of reports for **females** was **36.1 per 100,000 doses administered** and for **males** was **16.1 per 100,000 doses administered**.
- Females in the 20-39 year age group had the highest rate of reports for females.
- Females were more likely than males to report a serious adverse event following immunization, reporting adverse event biological differences between females and males.
- The highest and second highest rate of reports reporting adverse events has been observed in the United States, the United Kingdom, and other countries.
  - Health Canada, the Public Health Agency of Canada, provincial and territorial public health authorities will continue to monitor but have not identified this as a safety issue.

Figure 3. Total **adverse event reports** by age group, up to and including July 14, 2021 (n=10,167)

Data table: This chart contains the following data:

- Figure 3: Text Description

Serious and non-serious adverse events reported

All reports of adverse events following immunization received by Health Canada and PHAC are included in this report, regardless of whether they have been linked to the vaccine. This is because we need to look at all the data collected to see if any patterns or safety issues may be identified.

Health Canada, PHAC, the provinces and territories, and manufacturers continue to closely monitor the safety of COVID-19 vaccines. Serious events will be reviewed to determine if there is a new safety signal.

- For a new safety signal to be identified following immunization, Health Canada will take appropriate action. This could include updating the product information, communicating new risks to Canadians and healthcare providers or changing the recommended use of the product.
- The **10,167** individual reports represent **10,167** people who reported one or more adverse events. Among the **10,167** reports, **7,726** were non-serious and **2,441** were serious. Serious reports are presented in Figure 4.
- The majority of the serious reports are non-serious.

Figure 4. Serious **of the most frequently reported adverse events by vaccine type** (Top 5 adverse reactions), up to and including July 14, 2021 (n=27,197)

Please note that some reports include more than one adverse reaction, and therefore more than one adverse event.

- Figure 4: Text Description

Thrombosis with thrombocytopenia syndrome

- Thrombosis with thrombocytopenia syndrome (TTS) is characterized as blood clotting with low platelet levels. Vaccine induced thrombotic thrombocytopenia (VITT) also known as Vaccine Induced Prothrombotic Immunothrombocytopenia (VIPIT) is a variant of TTS that seems to be vaccine-induced due to the laboratory confirmed presence of platelet factor VIII4 antibodies.
- Up to and including July 14, 2021, there were **67 cases of TTS** in Canada with reports submitted to PHAC or to Health Canada. Of the 67 TTS cases:
  - 56 cases reviewed COVISHIELD/AstraZeneca COVID-19 vaccines, nine received a Pfizer vaccine, and two received a Moderna vaccine.
  - Of the 56 TTS cases following a COVISHIELD/AstraZeneca vaccine:
    - Symptoms started between 1 and 42 days after vaccination
    - Median age is 50 years (age range 30 to 80 years old)
    - 32 were males (median age 51 years (age range 34 to 71 years old)), 22 were females (median age 55 years (age range 30 to 80 years old)), the sex of one was unspecified
    - 52 reports following the first vaccine dose, and the dose number for four were unspecified
    - 19 reports following the second dose, and the dose number for one was unspecified
    - 12 reports following the first vaccine dose, 30 reports following the second vaccine dose, and the dose number for 14 was unspecified
    - 12 reports following the first vaccine dose, 30 reports following the second vaccine dose, and the dose number for 14 was unspecified
    - Evidence is evolving and investigations into the association between myocarditis/pericarditis and mRNA vaccines continue.

Capillary leak syndrome

- Up to and including **July 14, 2021, one case of capillary leak syndrome** has been reported to PHAC. The event occurred following a first dose of COVISHIELD/AstraZeneca vaccine.

Guillain-Barré Syndrome

- Up to and including **July 14, 2021, there are a total of 49 reports of GBS** in Canada. Of the GBS cases:
  - Symptoms started between 1 and 42 days after receiving a COVID-19 vaccine (median 14 days). Symptoms started 14 days following vaccination for 10 reports (median 14 days). Symptoms started 42 days after vaccination for 2 reports (median 42 days). 37 reports have been administered, and 5 cases received Moderna vaccine (0.06 reports per 100,000 doses administered).
  - Preliminary analysis shows that GBS following COVISHIELD/AstraZeneca COVID-19 vaccination is higher than the rate of GBS following Pfizer-BioNTech or Moderna vaccination. As well, the number of cases of GBS following COVISHIELD/AstraZeneca vaccination are higher than would normally be expected in the general population.
  - Among the 37 reports of GBS following COVISHIELD/AstraZeneca vaccine:
    - Symptoms started between 1 and 42 days after receiving a COVID-19 vaccine
    - Median age is 56 years (age range 46 to 71 years old)
    - 19 were males (median age 51 years (age range 46 to 69 years old)), 18 were females (median age 61 years (age range 46 to 77 years old)), the age and sex of one was unspecified
    - 19 reports following the first vaccine dose, and the dose number for 18 was unspecified
    - 18 reports following the second vaccine dose, and the dose number for 18 was unspecified

Deaths

- Up to and including **July 14, 2021**, a total of **112 deaths were reported** after the administration of a vaccine. Following medical case review using the WHO-UMC causality assessment category, it has been determined that:
  - 22 are still under investigation
  - 12 are not likely or unlikely linked to a COVID-19 vaccine
  - 32 deaths could not be assessed due to insufficient information.
  - 5 deaths followed a diagnosis of TTS (refer to the TTS section above)

Adverse events of special interest

Adverse events of special interest (AESI) are specified medically significant events that have the potential to be clinically associated with a vaccine product. They must be carefully monitored and confirmed by further special studies. AESI can be serious or non-serious and can include:

- Events of interest due to a concern associated with COVID-19 infection.
- Events of interest due to a concern (e.g. to the specific vaccine type or adjuvant).

The list of AESIs evolves into consideration the lists of AESIs from other expert groups, manufacturers and regulatory authorities:

- Brighton Collaboration
- Vaccine (2015) 33 Monitoring Readiness protocol

The AESI list changes based on the evolving safety profile of vaccines. It is important to recall that although these adverse events may occur after being immunized with a COVID-19 vaccine in Canada, they are rare and may not necessarily be related to the vaccine. Health Canada and PHAC review the reports to determine whether the vaccine may have played a role in the occurrence of these events.

Up to and including July 14, 2021, the most commonly reported AESI were Bell's Palsy and myocarditis/pericarditis (Table 1).

Table 1. Count **of AESI** reported **of special interest by vaccine type** (Top 5 adverse reactions)

AESI Category	AESI	Total number of events
Auto-immune diseases	Guillain-Barré Syndrome[1]	49
	Thrombocytopenia (low blood platelets)	61
	Subtotal	**109**
Cardiovascular system	Cardiac arrest	28
	Cardiac failure	13
	Myocardial infarction (heart attack)	52
	Myocarditis/Pericarditis (inflammation of the heart muscle and lining around the heart)	213
Subtotal		**296**
Circulatory system	Cerebral venous (sinus) thrombosis	15
	Cerebral thrombosis	5
	Cutaneous vasculitis	7
	Deep vein thrombosis	134
	Embolism	6
	Haemorrhage (bleeding)	35
	Pulmonary embolism	28
	Thrombosis (blood clot)	126
	Thrombosis with thrombocytopenia syndrome (blood clot + with low platelets)	57
Subtotal		**409**
Hepato-gastrointestinal and renal system	Acute kidney injury	19
	Liver injury	9
Subtotal		**28**
Nerves and central nervous system	Bell's Palsy/facial paralysis[2]	291
	Cerebrovascular accident (stroke)	102
	Transverse myelitis (inflammation of spinal cord)	18
Subtotal		**411**
Other system	Anaphylaxis[3]	114
	COVID-19[4]	102
Subtotal		**206**
Pregnancy outcomes	Fetal growth restriction	1
	Spontaneous abortion	3
Subtotal		**24**
Respiratory system	Acute respiratory distress syndrome	2
Subtotal		**2**
Skin and mucous membranes, bone and joints system	Chilblains	5
	Erythema multiforme (immune skin reaction)	13
Subtotal		**18**
All AESI categories	**Total**	**1,475**

- Includes reports meeting levels 1-4 of the Brighton Collaboration case definition.
- Includes reports meeting levels 1-3 of the Brighton Collaboration case definition.
- COVID-19 vaccines that are currently authorized **cannot cause an infection** because they do not contain the live virus that causes any of highly effective at preventing severe COVID-19 illness and death; no vaccine is 100% effective, and some COVID-19 cases will still occur. No vaccines that have a two-dose regimen, protection begins 14 days after the first dose, and 7 to 14 days after the second dose.

Please note that one report represents one person and may contain information on more than one adverse event of special interest.

Data notes

The data presented in this report are estimates and may not accurately represent national COVID-19 vaccine adverse events for the following reasons:

1. There may be delays in receiving reporting forms and processing reporting forms which may contribute to variations in the amount of reports captured weekly. Reporting delays may be due to questions investigating and reviewing each adverse event prior to submitting the information to PHAC. There are also limitations to reporting practices in Canada, including under-reporting, biases, and differing adverse event reporting practices across jurisdictions in Canada.
2. Information is collected on individuals for whom an report was submitted, not on the total number of individuals who experience a given adverse event, so not every adverse event is reported.
3. New information contained in this report may not be comprehensive but rather represents preliminary results of data received on a weekly basis.
4. Reporting jurisdictions may refer to gender as opposed to sex.
5. Information on adverse events following immunization is collected from provincial and territorial partners or their delegates, who receive the number of COVID-19 vaccines they administered are available.
6. The data presented in this report represent combined numbers from both CAEFISS and the Canada Vigilance program. Canada Vigilance receives reports directly from vaccine manufacturers, healthcare professionals and consumers. CAEFISS receives reports from regional public health authorities. Although data from these two surveillance systems are partially merged together, the individual programs are subject to different reporting requirements and definitions. It is also possible that the weekly report contains duplicate reports.
7. Adverse events following immunization reported to PHAC are coded using the Medical Dictionary for Regulatory Activities. For more information on priority terms for COVID-19 please see National Advisory Committee on Immunization statement.
8. Adverse events of special interest are assessed according to the Brighton Collaboration criteria (if available). For example, anaphylaxis reports that meet the Brighton Collaboration criteria (Level 1-3 are presented as "Anaphylaxis". All other others reports of anaphylaxis that meet the Brighton Collaboration Level 4-5 are included in the "other allergic reactions" category.

Acknowledgements

This weekly report would not be possible without the collaboration of federal, provincial and territorial public health partners as well as everyone taking part in the COVID-19 vaccination rollout in Canada.

We would also like to thank all individuals who took the time to submit an adverse event report for their contribution to vaccine safety in Canada.

Suggested citation

Public Health Agency of Canada. Canadian COVID-19 vaccination safety report. Ottawa: Public Health Agency of Canada; July 22, 2021. https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines/safety/

Related links

Related links

- Canadian Adverse Events Following Immunization and Surveillance System (CAEFISS)
- Immunization Monitoring Program ACTive (IMPACT)
- Canadian National Vaccine Safety Network (CANVAS)
- Canada Vigilance Program
- Drug Product Database
- Approved COVID-19 Vaccine list
- COVID-19 vaccines and treatments portal
- COVID-19 vaccination in Canada

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